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EXAMINER

TOMASZEWSKI, MICHAEL

ART UNIT PAPER NUMBER

3626

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/881,041

Applicant(s)

VONK ET AL.

Examiner

Mike Tomaszewski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Notice To Applicant***

1. This communication is in response to the amendment filed on 1/30/2006. Claims 1-20 are pending. Claims 1, 2, 4, 8, 13 and 15 have been amended.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne et al. (5,867,821; hereinafter Ballantyne), in view of Joao (6,283,761; hereinafter Joao), as applied in the previous Office Action, and further in view of Summerell et al. (5,937,387; hereinafter Summerell). Further reasons are given below.

(A) As per amended Claim 1, Ballantyne discloses a system for monitoring health-related conditions of patients, comprising:

- (1) at least one data access device adapted to provide a health care provider access to said computer network and said database (Ballantyne: abstract; col. 1, line 65-col. 2, line 63; Fig. 1-12 B).

Ballantyne, however, fails to disclose a system for monitoring health-related conditions of patients, comprising:

- (2) said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools; and
- (3) said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient.

Nevertheless, these features are old and well known in the art, as evidenced by Joao and Summerell. In particular, Joao and Summerell disclose a system for monitoring health-related conditions of patients, comprising:

- (2) said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30); and
- (3) said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient (Joao: abstract; col. 4, line 26-col. 5, line 54; col. Col. 41, line 56-col. 43, line 29; Fig. 1-15B).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne

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and Summerell with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

The remainder of claim 1 is rejected for the same reasons given in the prior Office Action and incorporated herein.

(B) As per amended claim 2, Ballantyne fails to expressly disclose a system as claimed in claim 1, wherein

- (1) said electronic assessment tools allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program.

Nevertheless, these features are old and well known in the art, as evidenced by Summerell. In particular, Summerell discloses a system as claimed in claim 1, wherein

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- (1) said electronic assessment tools allow a health care provider to monitor said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle and determine readiness of the patient for self-management under the selected treatment program (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

The remainder of claim 2 is rejected for the same reasons given in the prior Office Action and incorporated herein.

(C) Claim 3 has not been amended and is therefore, rejected for the same reasons given in the previous Office Action and incorporated herein.

(D) As per amended claim 4, Ballantyne fails to expressly disclose a system as claimed in claim 1, wherein:

- (1) said electronic assessment tools are quality of life assessment tools (Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30) (Examiner has noted insofar as claim 4 recites "selected from the group consisting of

Standard Form-36 (SF-36), Duke Activity Index, guidelines of the Diabetes Quality Improvement Project (DQIP), tools for specific disease state monitoring, depression scales, nutrition assessment tools, quality of life assessment tools," quality of life assessment tools is recited.).

Nevertheless, these features are old and well known in the art, as evidenced by Summerell. In particular, Summerell discloses a system as claimed in claim 1, wherein:

- (1) said electronic assessment tools are quality of life assessment tools  
(Summerell: abstract; col. 4, line 42-col. 6, line 59; Fig. 1-30).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Summerell with the combined teachings of Ballantyne and Joao with the motivation of providing a system and method for healthcare (Summerell: col. 2, lines 56-59).

- (E) Claims 5-7 have not been amended and are therefore, rejected for the same reasons given in the previous Office Action and incorporated herein.



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4. Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne, in view of Joao, as applied in the previous Office Action, and further in view of Seare et al. (5,557,514; hereinafter Seare). Further reasons are given below.

(A) As per amended claim 8, Ballantyne fails to expressly disclose a method for monitoring health-related conditions of patients, comprising:

- (1) generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs;
- (2) receiving economic data relating to protocols used in said treatment programs;
- (3) aggregating said patient health-related data, said clinical data and said economic data with information comprising population outcomes and generic standards of care; and
- (4) determining from said aggregated data recommendations for improving the treatment programs.

Nevertheless, these features are old and well known in the art, as evidenced by Joao and Seare. In particular, Joao and Seare disclose a method for monitoring health-related conditions of patients, comprising:

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- (1) generating from said accumulated health-related data clinical data comprising outcomes of said treatment programs (Joao: abstract; col. 4, line 26-col. 5, line 54; Fig. 1-15B);
- (2) receiving economic data relating to protocols used in said treatment programs (Seare: abstract; Fig. 1-15);
- (3) aggregating said patient health-related data, said clinical data and said economic data with information comprising population outcomes and generic standards of care (Seare: abstract; Fig. 1-15); and
- (4) determining from said aggregated data recommendations for improving the treatment programs (Seare: abstract; Fig. 1-15).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne and Seare with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Seare with the combined teachings of Ballantyne and Joao with the motivation of assessing treatment programs (Seare: abstract).

The remainder of claim 8 is rejected for the same reasons given in the prior Office Action and incorporated herein.

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(B) Claims 9-12 have not been amended and are therefore, rejected for the same reasons given in the previous Office Action and incorporated herein.

(C) Amended claim 13 substantially repeats the same limitations as unamended claim 13 and is therefore, rejected for the same reasons given in the previous Office Action and incorporated herein.

(D) Claim 14 has not been amended and is therefore, rejected for the same reasons given in the previous Office Action and incorporated herein.

5. Claim 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ballantyne, Joao, Russek (5,319,355; hereinafter Russek), as applied in the previous Office Action, and further in view of Soll et al. (US 2003/0055679). Further reasons are given below.

(A) As per amended claim 15, Ballantyne fails to expressly disclose a method for managing health-related conditions of patients, comprising:

- (1) determining whether each respective patient is suitable for participation in a treatment program;
- (2) wherein the determining step comprises the steps of:

- (a) obtaining agreement from a respective patient to participate in a treatment program; and
  - (b) receiving approval from a payer who will pay for the treatment program;
- (3) wherein the controlling step comprises the steps of:
  - (a) receiving health-related data for a respective patient comprising assessment of the patient's medical, psychological and environmental conditions;
  - (b) receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the assessment, the plan of care being used in the establishment of the treatment program for the patient.

Nevertheless, these features are old and well known in the art, as evidenced by Joao and Soll. In particular, Joao and Soll disclose a method for managing health-related conditions of patients, comprising:

- (1) determining whether each respective patient is suitable for participation in a treatment program (Soll: abstract; par. [0058]; Fig. 1-27);
- (2) wherein the determining step comprises the steps of:

- (a) obtaining agreement from a respective patient to participate in a treatment program (Soll: abstract; par. [0097]; Fig. 1-27); and
  - (b) receiving approval from a payer who will pay for the treatment program (Joao: abstract; col. 16, lines 38-65; Fig. 1-15B);
- (3) wherein the controlling step comprises the steps of:
- (a) receiving health-related data for a respective patient comprising assessment of the patient's medical, psychological and environmental conditions (Joao: abstract; col. 12, lines 43-50; col. 16, lines 38-65; Fig. 1-15B);
  - (b) receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the assessment, the plan of care being used in the establishment of the treatment program for the patient (Soll: abstract; par. [0058]; Fig. 1-27).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Joao with the combined teachings of Ballantyne, Russek and Soll with the motivation of facilitating the creation, management, quality, efficiency and/or effectiveness of healthcare services (Joao: col. 2, lines 38-54).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Soll with the combined teachings of Ballantyne,

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Joao and Russek with the motivation of providing a system and method of healthcare (Soll: par. [0014]).

The remainder of claim 15 is rejected for the same reasons given in the prior Office Action and incorporated herein.

(B) Claims 16-20 have not been amended and are therefore, rejected for the same reasons given in the previous Office Action and incorporated herein.

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 1, 2, 8 and 15 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant's arguments filed on 1/30/2006 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 1/30/2006.

(A) On pages 8 and 9 of the 1/30/2006 response, Applicant argues that neither Ballantyne nor Joao nor Russek disclose or suggest the self-management tools and assessment tools as claimed in claim 1 for facilitating integration of a treatment program into a patient's lifestyle. Applicant argues further that neither Ballantyne nor Joao

monitor a patient's questions or responses to questions concerning health or treatment, nor use such information to determine progress on a treatment program and whether information needs to be conveyed to the patient regarding the treatment program.

In response, Examiner points out that these arguments are moot because Examiner has relied on Summerell to reject these features. See rejection above for details.

(B) On pages 9 and 10 of the 1/30/2006 response, Applicant argues Joao is silent regarding using financial or economic data in aggregation with patient health-related data, clinical data and information comprising population outcomes and generic standards of care, and determining from the aggregating data recommendations for improving the treatment programs.

In response, Examiner points out that these arguments are moot because Examiner has relied on Summerell to reject these features. See rejection above for details.

(C) On page 10 of the 1/30/2006 response, Applicant argues the applied references in the Office Action do not disclose or suggest such an enrollment process for establishing a treatment program.

In response, Examiner respectfully submits that the Joao reference does indeed disclose and suggest, at least in part, the enrollment process for establishing a treatment program, as recited by Applicant's claims. In particular, Joao discloses and

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suggests receiving approval from a payer who will pay for the treatment program (Joao: abstract; col. 16, lines 38-65; Fig. 1-15B); and receiving health-related data for a respective patient comprising assessment of the patient's medical, psychological and environmental conditions (Joao: abstract; col. 12, lines 43-50; col. 16, lines 38-65; Fig. 1-15B).

As per the remaining limitations, Examiner has relied upon Soll. See rejection above for details.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied art teaches a therapeutic behavior modification program, compliance monitoring and feedback system (6,039,688).

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not



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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MT



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